



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

11/12/97
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-04

October 31, 1997

Jack T. Stephens, President
Lakeland Regional Medical Center
1345 Lakeland Hills Boulevard
Lakeland, Florida 33805

Dear Mr. Stephens:

Inspection of your methadone inpatient detoxification program on August 21-25, 1997, by Food and Drug Administration (FDA) Investigator Scintone Robinson, revealed violations of Title 21, Code of Federal Regulations, Part 291 (21 CFR 291), Conditions for the Use of Narcotic Drugs.

Eight patients admitted to your inpatient detoxification program had no "Consent to Treatment with an Approved Narcotic Drug" (Form FDA 2635) on file. Your program is approved to perform inpatient detoxification only. However, your program performed outpatient detoxification for patient #00-14-22-64 after discharge from the hospital. Your program also failed to account for all methadone dispensed by the medical center pharmacy. The methadone detoxification dispensing log shows that on June 30, 1997, four units of methadone, 10 mg each, lot #952132, were dispensed from the pharmacy at 8AM, 12PM, 5PM, and 10PM for patient #00-11-43-06. However, the medication administration record for this patient fails to document and/or account for the 10 mg dose of methadone scheduled to be given to the patient at 10PM. A copy of the Inspectional Observations (Form FD-483), issued to your methadone program medical director at the conclusion of the inspection is enclosed.

The above identification of violations is not intended to be an all-inclusive list of deficiencies in your methadone program. It is your responsibility, as president and chief executive officer of the medical center, to ensure that your narcotic treatment program operates in compliance with all applicable federal and state laws and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice.

Mr. Jack T. Stephens

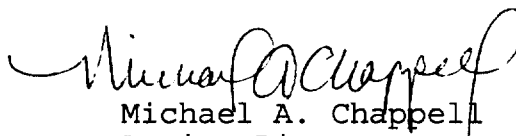
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You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If correction cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U. S. Food and Drug Administration, Florida District, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 263.

Sincerely,


Michael A. Chappell
Acting Director
Florida District

Enclosure